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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872

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Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

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02/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/085,738	Applicant(s) WEADOCK ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 3,10,11,16-28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,14,15,29-33 and 38-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/24/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 11/24/08

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 11/24/08 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1,4-9,14,15,29-33 and 38-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,713,441 to Thomas in view of US 6,743,243 to Roy et al. and in further view of US 6,726,923 to Iyer et al.

(claim 1) Thomas discloses a device for creating an end to side anastomosis between a first vessel **21** and a second vessel **24**, the device comprising a substantially cylindrical body (**22,23**) the body formed from an open construction material (col. 2, ll. 22), the body comprising an inner surface defining a through opening configured to receive the first vessel **21**, the body further comprising a proximal surface configured to appose an outer surface of the second vessel **24**. Thomas is silent with regards to the device being formed from resorbable sponge material and having first and second securing means.

Roy discloses a similar device for creating an end to side anastomosis between vessels, the device comprising an extravascular body (shown in Fig. 1) having an inner surface and outer surface, and adhesives on the inner surfaces of the first tubular member **1** and the inner surface of the second tubular member **2** (col. 5, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Thomas to use the adhesives of Roy as it will provide additional securing means between the first vessel and the second vessel.

The modified device of Thomas is still silent with regards to the body being fabricated from a resorbable sponge. However, Iyer discloses that it is known to form anastomosis support devices from biocompatible, biodegradable, resorbable matrix material such as collagen, which can be made into a sponge material (col. 8, ll. 56-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the device of Thomas from collagen because collagen can be used to imbibe a drug in order to provide medicaments to the anastomosis site.

(claims 4-5, 7-9) Roy discloses the inner surface of the tubular element **2** is provided with adhesive to seal the element onto the vessel. Therefore, the modified device of Thomas would have the same arrangement. The adhesive would also be disposed in the sponge material after being modified by the Iyer reference.

(claim 6) Thomas is silent with regards to the use of a balloon catheter. However, the use of a balloon catheter during anastomotic surgery is well known in the art. For example, Roy discloses a balloon catheter that is used to attach the tubular element to the blood vessel (col. 6, ll. 7-9). Therefore, it would have been obvious to use a balloon catheter with the device of Thomas because it would help stabilize the first vessel against the second vessel.

(claims 14 and 15) The modified device of Thomas will be formed with the collagen disclosed by Iyer, which includes a medicament, such as an anastomosis modulating agent (see abstract).

(claim 29) Thomas discloses the method of providing a substantially cylindrical body as recited in the claims and in the rejection to claim 1 above. Thomas is silent

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with regards to the steps of providing adhesives, or with the body made from a resorbable sponge material. However, providing the adhesives and forming the body from resorbable sponge material would be obvious to one of ordinary skill, as set forth in the rejection to claim 1.

(claims 30, 31 and 38-41) The modified device of Thomas would have the first vessel attached to the body opening via adhesives and the second vessel is attached to the portion of the outer surface of the body via adhesives; the second vessel has a hole and the body is positioned over the hole as a "cap"; wherein a balloon catheter is used (as recited in the rejection to claim 6 above).

(claim 32 and 33) Thomas is silent with regards to when the hole is formed. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to either have the hole formed subsequent to attaching the portion of the second vessel to the body or prior to attaching the portion of the second vessel to the body since a hole must necessarily formed in order to create an end-to-side anastomosis and that the step of when the hole is formed would be a mere design choice.

(claims 42 and 43) The blood flows intraluminally through the first and second vessels.

(claims 44-45) Thomas fails to teach the device having the shape disclosed in the claims (substantially perpendicular with a through opening having an acute angle). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Thomas to have the recited shape since it

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has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Furthermore, the applicant has not provided any criticality for the recited shape since the applicant also provides a shape for the body having an acute angle relative to the outer surface of the second vessel. Therefore, the shape of the elongated body would be a mere obvious design choice to one of ordinary skill in the art.

(claims 46-47) Thomas discloses the axis of the cylindrical body forming an acute angle relative to the outer surface of the second vessel.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773